

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 444.81507004	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/GB2004/002866	International filing date (day/month/year) 02.07.2004	Priority date (day/month/year) 04.07.2003	
International Patent Classification (IPC) or national classification and IPC A61K35/74			
Applicant NORFERM DA			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 29.04.2005		Date of completion of this report 08.07.2005	
Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>		Authorized Officer Peris Antoli, B Telephone No. +49 89 2399-	



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-13 as originally filed

Claims, Numbers

1-16 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 9 (industrial applicability); 1-6, 8-10, 12-15 (all partially); 16-17 (completely)

because:

- ☒ the said international application, or the said claims Nos. 9 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 1-6, 8-10, 12-15 (all partially); 16-17 (completely)
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-11, 13-15
	No: Claims	12
Inventive step (IS)	Yes: Claims	1-11, 13
	No: Claims	12, 14, 15
Industrial applicability (IA)	Yes: Claims	1-8, 10-15
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
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1. Reference is made to the following documents:

- D1: GB-A-1 319 114 (1973-06-06)
- D2: WO-A-01/49277 (2001-07-12)
- D3: EP-A-0 404 300 (1990-12-27)
- D4: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; November 1975 (1975-11), WEAVER T L ET AL: "Whole-cell and membrane lipids of the methylotrophic bacterium *Methylosinus trichosporium*." XP002302098 Database accession no. NLM810477
- D5: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1991, BOWAN J P ET AL: "PHOSPHOLIPID FATTY ACID AND LIPOPOLYSACCHARIDE FATTY ACID SIGNATURE LIPIDS IN METHANE-UTILIZING BACTERIA" XP002302099 Database accession no. PREV199191111571
- D6: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1993, PELTOLA PETRI ET AL: "Effect of copper on membrane lipids and on methane monooxygenase activity of *Methylococcus capsulatus* (Bath)" XP002302100 Database accession no. PREV199396092064
- D7: WO 01/60974 A (LARSEN JAN ; GOLDING LOUISE (GB); JOHANNESSEN ARILD (NO); KLEPPE GUNNA) 23 August 2001 (2001-08-23)

Re Item IV

Lack of unity of invention

2. In line with the objection raised in the search report, the international preliminary examining authority is of the opinion that the present application (-with the claims presently on file-) does not comply with the requirements of unity of invention as set forth in Rule 13.1 PCT, for the following reasons:

2.1 **Present claims 1-17 are directed to**

- (1) medicaments comprising microbial lipids [claims 10, 11, 12 (part), 13, 15 (part)] and the use of said medicaments for reducing plasma cholesterol or the ratio LDL/HDL in plasma [claims 1, 4-8 (part), 9];
- (2) medicaments comprising microbial lipids [claims 10, 11, 12 (part), 13, 15 (part)]

and the use of said medicaments for increasing plasma DHA (docosa-hexaenoic acid) [claims 2, 4-8 (part)];

- (3) medicaments comprising microbial lipids [claims 10, 11, 12 (part), 13, 15 (part)] and the use of said medicaments as immuno-protectant agents [claims 3, 4-8 (part)];
- (4) foodstuff comprising microbial lipids [claims 14, 15 (part)];
- (5) food products harvested from animals fed with a microbial lipid [claims 16-17].

3. The common concept linking the aforementioned five different aspects of the claimed subject matter is "microbial lipids and their use as food or medicine"

3.1 Said concept is neither new nor inventive, because compositions (for medical or dietary use) comprising microbial lipids are already known from the state of the art see e.g. D1 to D3 below.

D1 (see e.g. claims 1, 4 and 8 in conjunction with c. 2, l. 9-11) discloses a method for preparing microbial lipids, including phospholipids, and their use as food or for medicine.

D2 (see e.g. claims 1, 8 or 11 and examples 1-3) discloses bacterial lipids, including phospholipids, as well as their use in medicine for increasing immune effects and their use as food additive.

D3 (see e.g. claims 1, 7, 10, 14, in conjunction with p. 4, l. 27-29 and Table 4) discloses bacterial lipids, including phospholipids such as phosphatidylethanolamine, their therapeutic use for reducing cholesterol, and their use as animal feed, e.g. as chicken feed to produce low-cholesterol eggs.

3.2 Thus, each of the five different aspects of the claims specified above (see point 2.1) is considered to relate to a separate invention or groups of inventions which are not so linked as to form a single inventive concept.

4. Although the claimed subject matter does not comply with the requirements of

unity of invention, due to the objections under Art. 5-6 PCT raised below, this authority has chosen, according to rule 68.1 PCT, not to invite the applicant to restrict the claims or to pay additional fees.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

5. **Claim 9** relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).
6. Independent **claims 1, 2, 3, 9, 10, 12, 14, 15 and 16** lack clarity and support of disclosure within the meaning of Article 5 and 6 PCT because scope of the features "*microbial lipid(s)*" or "*microbial lipid extract*" used in said claims is not supported by the technical contents of the application. Indeed, said features encompass lipids from an extremely large number of microorganisms (including bacteria, yeast or fungi), whereas the application (see in particular examples 1-2) provides support within the meaning of Article 6 EPC and/or disclosure within the meaning of Article 5 EPC for only a very limited number bacteria, namely methanotrophic bacteria. The same applies to the dependent **claims 4-6, 8, 13 and 17**.
Furthermore, the application provides no support any particular technical feature of food products as claimed in present **claims 16-17**.
- 6.1 In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole breadth of the features "*microbial lipid(s)*" or "*microbial lipid extract*" and over the products according to claims 16 and 17 is impossible.
Consequently, the search has been carried out as if the aforementioned unclear features "*microbial lipid(s)*" or "*microbial lipid extract*" in claims 1-6, 8-10, and 12-15 had been restricted to "*lipids of lipid extracts from methanotrophic bacteria*". Claims 16-17 have not been searched at all.
7. According to Rule 66.1(e) PCT, no international preliminary examination will be carried out in respect of the subject matter which is not covered by the search

report.

7.1 Thus, for the purpose of this report, **claims 1-15 had been read as if they were restricted to "*lipids of lipid extracts from methanotrophic bacteria*".**

7.2 For **claims 16-17 no opinion** will be established.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Novelty

8. The subject matter of **claim 12 is not new** because lipids from methanotrophic bacteria, including lipids from *Methylococcus* are already known from the state of the art; see e.g. **D4-D6**.

Claim 12 does therefore not meet the requirements of Art. 33(2) PCT.

9. The remaining **claims 1-11 and 13-15** meet the requirements of Art. 33(2) PCT because their subject matter is formally new over the prior art cited in the search report.

Inventive step

10. **Claims 14 and 15 (in part)** do not meet the requirements of Art. 33(3) PCT for the reasons set out below.

10.1 D7 (see e.g. claims 17-19 in conjunction with p. 13, l. 5-8) discloses a food grade product for human and/or animal consume, said product being a homogenised single-cell protein material obtained from the methanotrophic bacterium *Methylococcus capsulatus*. As indicated in D7 (see e.g. p. 10, l. 1.6) said product also comprises from 5 to 20 % fat (i.e. lipids).

10.2 In view of the known suitability of cellular material from methanotrophic bacteria for human/animal consume, wherein said material contains lipids (see D7 above), those skilled in the art aware of the teachings of D4-D6, would have found it obvious to prepare and use pure lipid or lipids extracts from methanotrophic bacteria with the aim of producing food or nutraceutical products for human/animal consume.

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10.3 Thus, no inventive step can be recognised for the subject matter of claim 14 and 15 (in part) in view of the teachings of D7 in combination with any of D4 to D6.

11. **Claims 1-11, 13 and 15 (in part)** meet the requirements of Art. 33(3) PCT because none of the documents cited in the search report teaches or suggests any possible medical use of lipids from methanotrophic bacteria.

Industrial applicability:

12. Claims 1-8, 10-15 satisfy the criterion set forth in Art. 33(4) PCT because their subject matter is susceptible of industrial application.